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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/539,874 | 04/21/2006 | Thomas Plath | 7003/40 | 7118 |

27774 7590 02/05/2008

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| EXAMINER | |
|---|---|
| NATARAJAN, MEERA | |
| ART UNIT | PAPER NUMBER |
| 1643 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 02/05/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/539,874 | PLATH ET AL. | |
| | Examiner | Art Unit | |
| | Meera Natarajan | 1643 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11/13/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *5-8 and 10-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 9, 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group I, claims 1-4, 9, and 14 in the reply filed on 11/13/2007 is acknowledged. The traversal is on the ground(s) that the references stated in the restriction requirement mailed 09/10/2007 "does not take away from the fact that a single inventive concept ties all of the claims together, i.e., modulating TRPM8 activation and/or inhibition". This is not found persuasive because the stated reference Bessette et al. teach pharmaceutical compositions containing plant essential oils, natural or synthetic, or mixtures or derivatives, such as menthol, for the prevention and treatment of soft tissue cancer in mammals. Therefore, the special technical feature recited in claim 5 is not novel. The term "galencially" is not defined in the instant specification and is therefore broadly interpreted to be defined as what is stated in the American Heritage Dictionary. Applicant's argue that "galencially prepared" is a well-known term in the pharmaceutical industry and is defined as a preparation which formulates pharmaceutical compounds for administration in suitable forms for intravenous, intraperitoneal or intramuscular injection or infusion. Bessette et al. also disclose that the pharmaceutical compositions may be prepared for administration via intravenous, intraperitoneal or intramuscular injection or infusion and therefore read on applicant's interpretation of "galencially prepared". The requirement is still deemed proper and is therefore made FINAL.

2. Claims 5-8 and 10-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable

generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/13/2007.

3. Applicant's failed to elect a species for "substance" listed in claims 3, 5, and 9 and "additive" listed in claim 4 in the response filed on 11/13/2007. However, after further consideration the species requirement has been withdrawn for substance, additive, and disease.

4. Claims 1-4, 9 and 14 will be examined on the merits.

### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-4, 9 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 recites "physiologically active dose" in line 2 of the claim. It is unclear what is meant by "physiologically active". Does applicant mean a dose that causes a physiological reaction, a dose that increases concentration of TRPM8, etc? Clarification is suggested.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-4, 9 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inhibiting growth of prostate cancer tumors in which TRPM8 is overexpressed, comprising administration of a physiologically active does of a pharmaceutical composition comprising a TRPM8-activating substance or mixtures containing a TRPM-8 activating substance, consisting of the group listed in Claim 3, does not reasonably provide enablement for a method for treating *any* tumor disease in which TRPM8 is overexpressed, comprising administration of a physiologically active does of a pharmaceutical composition comprising *just any* TRPM8-activating substance or mixtures containing a TRPM-8 activating substance. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

10. In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered.

11. The claims are broadly drawn to a method for treating any tumor disease in which TRPM-8 is overexpressed, comprising administering a TRPM8 activating substance. The specification only provides a working example of a HEK293 embryonic kidney cell line, overexpressing TRPM8, injected into the prostate of mail hairless mice as a tumor models and does not support treating the broad scope of any tumor disease. Tsavaler et al. (Cancer Research, Vol 61(9), pp.3760-3769, 2001) disclose TRPM8 (also known as Trp-p8) mRNA was also expressed in a number of nonprostatic primary tumors of breast, colon, lung, and skin origin, whereas transcripts encoding TRPM8 were hardly detected or not detected in the corresponding normal human tissues (see Abstract). Therefore, undue experimentation would be required to support an enablement for the broad scope of the claim to include all tumor diseases and to determine whether administering a TRPM8 activating substance would inhibit tumor growth.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 3, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Bessette et al. (WO/2000/033857) as evidence by Andersson et al. (J. of Neuroscience Vol. 24(23), pp.5364-5369, 2004).

14. The claims are drawn to a method for treating tumor diseases in which TRPM-8 is overexpressed, comprising administration of a galencially prepared pharmaceutical composition comprising a TRPM-8 activating substance or mixtures containing a TRPM-8 activating substance

15. Bessette et al. teach a method for treating soft tissue cancers in mammals, comprising administering pharmaceutical compositions containing plant essential oil compounds, including mixtures or derivatives thereof. Bessette et al. disclose several plant essential oils including menthol and methyl derivatives (see p. 3, last paragraph). Andersson et al. provide evidence that menthol activates TRPM-8. Bessette et al. further disclose "pharmaceutically acceptable carriers, adjuvants and vehicles that may be used in the pharmaceutical compositions of the invention", including polyvinyl pyrrolidone, "which are used to enhance delivery of therapeutical-effective plant essential oil compounds of the present invention" (see p. 5-6 last paragaraph). Besette et al. also disclose the pharmaceutical compositions can be administered in a variety of ways (see p. 6, 1st paragraph) and combined with a carriers, lubricating agents (p. 6, last paragraph), sweetening and /or flavoring agents (p. 6 last sentence), and solubilizing or dispersing agents (p. 7, 3rd paragraph).

***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. Claims 1-4, 9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessette et al. (WO/2000/033857) as evidence by Sella et al. (BJU International, Vol. 100(3), pp.533-555, 2007), Damron et al. (Ann. Surg. Oncol. Vol. 7(7), pp.526-534, 2000) and Meittinen et al. (Eur. J. Cancer Vol. 38(S39-51), 2002).

19. The claims are drawn to a method for treating prostate tumors and gastrointestinal tract or respiratory organ tumors which overexpress TRPM8 comprising administration of a physiologically active does of a pharmaceutical composition comprising a TRPM8 activating substance or mixtures containing a TRPM8 activating substance.

20. The teachings of Bessette et al. have been presented in the 102(b) rejection set forth above. Bessette et al. does not teach a method of treating prostate cancer. However, Bessette et al. does disclose treating soft tissue cancers, in particular breast cancer. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention was made to use the method taught by Bessette

et al. to potentially treat other types of cancers, such as prostate cancer, gastrointestinal and respiratory tumors which often metastasize to soft tissue (see evidentiary references). One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success to extend the method taught by Bessette et al. to other soft tissue carcinomas including prostate and lung cancer.

***Conclusion***

21. Claims 1-4, 9 and 14 are rejected.

22. No claim is allowed.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meera Natarajan whose telephone number is 571-270-3058. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business

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MN

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER